Probabilistic Models and Methodologies: Advancing the Ecological Assessment Process in EPAs Office of Pesticide Programs, Edward Odenkirchen, OPPTS

Pesticides are administered over five million acres at an application rate of one lb./acre/application to a cotton or corn field. The adverse effects are being measured with no exposure data specific to the compound. However, toxicity data was developed, and from there, Risk Quotients (similar to a hazard quotient) were developed. A methodology was developed to assess exposure, but it was reviewed and only considered to be a screen upon which regulatory decisions cannot be based. The process was then revised.

Initiative to Revise the Ecological Assessment Process:

- Phase I: develop a strategy for risk assessment refinement:
  - ECOFRAM
  - A strategy for risk assessment refinement and a compendium of tools and methods for EPA consideration was produced.
  - Results at various stages of development were presented in scientific meetings and to risk managers.
  - Draft reports were issued in May 1999.
  - There was participation in a peer review workshop in June 1999.

- Phases II and III: development of an Implementation Plan and PRA tools and methods; implementation:

  Phase II involves
    - implementing a new tiered approach to ecological assessment, which includes probabilistic tools and methods at higher tiers,
    - using more realistically to reflect actual use scenarios and field conditions,
    - building upon existing data requirements,
    - focusing additional data requirements of reducing key areas of uncertainty, and
    - identifying candidates for mitigation measures early in the process.

- Phase II and III, initial efforts involved
    - conducting a technical evaluation of ECOFRAM reports and workshop comments,
    - preparing a time line and activity plan for implementation, and
    - preparing conceptual papers describing a tiered approach to incorporating PRAs, which were presented to SAP in April 2000.

The methods that produce results in a Superfund probabilistic risk assessment do not necessarily work for pesticides, because the exact same data set exists for almost every single chemical. Therefore, a method was needed to narrow the definition for the statement of risk.

Tiered approach to ecological risk assessment: a conceptual process

- There are four levels of refinement which describe the complexity of the assessment.
- There are less complex assessments at lower levels based on more conservative assumptions and generic data.
- The assessments at higher levels are more complex, representing increasingly realistic biological and exposure scenarios.
- Guidance will be developed on moving to higher levels.

Current efforts: proposed PRA models and methodologies.

- Efforts represent EFED's initial effort to develop and incorporate probabilistic methods into assessment process.
- Proposed models and methodologies offer a more refined assessment than a deterministic screening level methodology.
- PRA models and methodologies provide initial expression of probability and magnitude of effects.
- PRA model distributions are developed for major exposure and effects variables.
- Variables are combined using Monte Carlo analysis.

The RQs were compared, and a decision could be made immediately, but what was being compared had a high degree of uncertainty. In conjunction with the Canadians, the RAs for birds and plants are currently being completed. The RAs for mammals will be addressed next.

Level I assessments look at RQs, uncertainties, toxicity, etc. Level II assessment uses a lot of generic assumptions and is based on models which have been developed.

Highlights of proposed models:

- Terrestrial:
    - quantifies acute mortality based on oral exposure from food and water taken in treated fields
    - focal species are used to provide more realistic and appropriate biological scenarios
- Aquatic:
    - quantifies acute mortality and chronic exceedences to fish and aquatic invertebrates
    - provides additional examination of specific high acreage scenarios and regional differences within a crop
    - estimates probability and magnitude based on standard test species and more sensitive, untested generic species

The three types of data used include

- acute oral dose,
- chronic oral dose, and
- acute toxicity.

Terrestrial model problem formulation:

- Risk Manager Questions (Steve Johnson 1997, currently Acting Assistant Administrator)
    - What are the effects of concern?
    - What are the magnitude and probability of these effects?
    - Are the effects seen across different species?
    - Will there be population effects?
    - Will the effects influence the density and diversity of the species?
    - How confident are we in our estimates of effects?
    - Etc.
- The model can be characterized as a species specific model which addresses acute mortality over a defined exposure window.
- The spatial scale is at the field level, such that the field and surrounding areas are assumed to meet habitat requirements for each focal species (although, the focal species may need to be changed).

– Temporal scale is for exposure immediate to and following a single application (most pesticides are applied 2-3 times and up to 8 times per year).

Basic structure: risk is a function of exposure toxicity

Elements of the pilot avian risk model:

– The scenario is a single treated field, single species, or a typified bird from a specific feeding guild.
– individual risk = f(exposure, toxicity) = M[" +log_{10}$ (uptake)]
– There is a random distribution of pesticide uptakes (ug/day) in exposed populations.
– Current focus is on variation across bird populations; uncertainty is treated through scenario analyses.
– The endpoint is acute mortality.
– Pathways of concern are contaminated food and water sources.

Pesticide Intake Model: Total pesticide intake at time *t* is the sum of the intakes across food groups and water sources at time *t* PLUS what was retained from the total intake from an earlier time *t*-1.

Very little data on the toxicokinetics of these compounds exists. Some chemicals are quickly absorbed and quickly excreted, and some are not. Therefore, using the same model for both compounds would lead to the potential for risk to be grossly underestimated.

From the Wildlife Exposure's Handbook: pesticide intake from food sources

Basic formula: $U_{\text{food}}(t) = \text{E}_{\text{k}}\, C_{\text{k}}(t)$ x $TDIR$ x DF_{k} x $*(t)$ x FC_{k}

where:

$C_{\text{k}}(t)$	=	pesticide concentration in kth food group
$TDIR$	=	total daily food intake
DF_k	=	fraction of diet for kth food group
$*(t)$	=	1 if bird is on the treated field; = 0 otherwise
FC_{k}	=	fraction of kth food source actually contaminated

A decision must be made about the percentage of time a bird is spending in the field and spending feeding in the field. There are different pesticide application methods, which lead to high variability in treatment, and therefore, exposure.

Pesticide intake from water sources:

Basic formula: $U_{\text{water}} = C_{\text{water}}$ x $DWIR_{\text{adjusted}}$ x F_{t}

where:

C_{water}	=	pesticide concentration in water source
$DWIR_{\text{adjusted}}$	=	drinking water intake rate, adjusted for water intake from food sources
F_{t}	=	water fraction consumed in time period

Controversy exists on how the birds are getting their water, because exposure will differ with the source (e.g., puddles vs. gleaning water/dew off of grass blades).

Exposure Parameters: The major exposure parameters for selected focal species in the model are

– food habits of,
– body weight,
– daily ingestion rates of food and water,
– frequency of feeding and drinking on sprayed fields,
– residues on food and water sources, and
– degradation rates of food and water residues.

Residues on food and water sources were calculated from the Uptake Translocation Accumulation Monitoring Transformation Database (UTAB) and a paper completed by Fletcher.

The pilot model uses a log-probit dose-response function from 340 compounds for tiered effects, which is characterized in terms of an intercept and a slope. Cumulative exposure is already accounted for.

The model accounts for interspecies' differences in sensitivity by looking at food habits of select focal species and
– normalizing all tested species results by body weight,
– constructing a log normal distribution of LD50s,
– adjusting for small sample size, and
– selecting scenarios of sensitivity 5th, 50th, and 95th percentiles.

The model uses the mean slope of the dose-response relationships to account for intraspecies' sensitivity.

Interpreting the risk output:
– When the model is run through 10,000 simulations (trials), the resulting 10,000 risks are interpreted as the individual risks of mortality to 10,000 randomly selected birds.
– The CDF represents a numerical estimate of the cumulative distribution of individual risks in a large population of birds in which each bird has a unique risk.
– The distribution of individual risks in a subpopulation N of a larger population P follows the compound Poisson-binomial distribution.
– For estimating the large sample average properties of bird populations, we use the mean individual risk estimated in the Monte Carlo simulation, such that

$$\langle R \rangle = \frac{1}{N} \sum_{k=1}^{N} R_k \quad k = 1,2,\ldots,N \ trials$$

This is a work in progress, and several parameters which may be important to risk estimates have not been addressed, including
– other routes of exposure than oral (e.g., dermal and inhalation),
– accounting for gorging behavior (as in migratory birds),
– considering the possibility of avoidance behavior,
– variables that affect sensitivity (age, environmental factors, etc.),
– other taxonomic groups, mammals, reptiles, amphibians,
– sub-lethal and indirect effects,
– local level effects,
– population effects, and
– community level effects.

A GIS tool is used to relate treatment of a crop across a mosaic of other fields that could be treated with the same compounds at the same time or in different time periods.

Variability vs. uncertainty:

- Variability - refers to observed differences attributable to heterogeneity or diversity in a population or exposure parameter
- Uncertainty - less well defined; refers to imperfect knowledge concerning the present or future state of the system under consideration

Next Steps:

- Continue model development for
  - looking at other routes of exposure,
  - improved residue modeling (puddles, dew, food items),
  - characterizing and propagating uncertainty,
  - exploring alternative sensitivity analyses, and
  - exploring alternative software platforms.
- Engage risk managers
  - to achieve a level of sufficient information,
  - for establishing scope (temporal and geographical), and
  - to determine needs in a decision making process.
- Develop training for staff scientists.
- Begin to employ models in the Agency's assessments, where useful.
- define additional research needs to reduce uncertainty in the models (so that decisions can be made with more confidence).

A study needs to be completed on how the different bird species detect their prey (e.g., motion feeders vs. color feeders or shape feeders) and how intoxication of that prey affects their feeding choices.

Projects initiated to support PRA development include

- having a contractor prepare a report on methods development for inhalation and dermal exposure models,
- encouraging ORD initiative to investigate modification to the reproduction effects' protocol,
- encouraging ORD initiative to carry the model forward to predict population vectors,
- re-analysis of UTAB and Fletcher data on food item residues,
- having a contractor test the OECD avian dietary test protocol,
- a USGS cooperative agreement to examine screening risk predictions and observed effects in the field,
- a USGS cooperative agreement to investigate orchard invertebrate residues and sources of non-dietary exposure in resident birds, and
- securing a research grant to develop techniques for determining bird time budgets in agro-environments.

Concluding remarks:

- All models are wrong, but some are useful.
- The purpose of computing is insight, not numbers.

OPPTS is working with the American Bird Conservancy to develop a more specific methodology for recording avian incident information and the development of bio-markers. The ability of models to predict risks at very, very low concentrations of contaminants outweighs our ability to measure contaminants at those concentrations. OPPTS is legally mandated to make decisions for registering and re-registering all pesticides. A schedule exists for re-registering the different pesticides, and OPPTS has a deadline to determine its suitability. If the chemical is approved for re-registering, then it will not be available for reevaluation for 15 years.